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August 23, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
USA

Regarding: Foreign Establishment Registration and Listing Proposed Rule [Docket Number 98N-1215]

The following comments are provided in connection with the Food and Drug Administration proposal to amend its regulations pertaining to the registration of foreign establishments and the listing of human drugs, animal drugs, biological products, and devices. The comment period for this proposal was recently reopened following comments received from the Canadian government. The proposal would require foreign establishments whose products are imported or offered for import into the United States to register with FDA. The proposal would also require foreign establishments to identify a United States agent and would describe some of the agent's responsibilities.

Under the proposed rule, the U.S. agent would, upon request from FDA, assist FDA in communications with the foreign drug establishment, such as responding to questions about the establishment's products that are imported or offered for import into the United States, and assisting FDA in scheduling inspections of the foreign drug establishment. The proposal would also consider information or documents provided by FDA to the United States agent to be equivalent to providing the same information to the foreign drug establishment. This provision would apply when the agency is unable to contact the foreign manufacturer directly or expeditiously.

As currently written, there is no option in the proposed rule to allow for a waiver or exemption from the requirement to identify a U.S. agent in cases where the FDA has had no difficulty with regular and direct communication with a particular foreign drug establishment. It seems redundant and unnecessary to impose an additional regulatory and economic burden in situations where there has not previously been any communication difficulties. As an example of one such company we are concerned that this requirement will impede rather than enhance communications simply by virtue of having a "middleman" involved. Furthermore, while it is concluded that "the proposed rule ...should not have a significant economic impact on a substantial number of small entities", the analysis considers only the relatively minor costs of preparing an establishment registration and fails to include the much more significant costs incurred in retaining a United States agent.

Such an exemption should take into consideration whether the foreign establishment is located in

an English speaking country and what the record of communications has been to date, including the frequency of FDA inspections where applicable. The onus could be put on the foreign drug establishment to apply for and justify a waiver.

We are therefore requesting that the proposed rule be amended to provide for the option of a waiver from the requirement to identify a U.S. agent. Thank you for consideration of these comments.

Sincerely,

CANGENE CORPORATION

Elizabeth Wishart, B.Sc., M.B.A.
Manager, Regulatory Affairs

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